moor instruments
innovation in microvascular assessment

K112826

moorVMS-OXY 510(k) Summary

OCT 10 2012

Submitter:	Moor Instruments Ltd
Address:	Millwey Axminster, Devon EX13 5HU, United Kingdom
Telephone:	(+44) 1297 35715
Fax:	(+44) 1297 35716
Contact:	Xiabing Huang
Contact title:	Managing Director
E-mail:	xhuang@moor.co.uk
Date:	September 26th, 2011
Model Name:	moorVMS-OXY Tissue Oxygen and Temperature Monitor
Model Number:	moorVMS-OXY
Common Name:	Tissue Oximeter
Classification Name:	Oximeter, 21 CFR 870.2700
Regulatory Status:	Class II
Establishment Reg No:	8043564
Type of 510(k):	Traditional
Reason for submission:	New device
Predicate Devices:	T-Stat 303 Microvascular Tissue Oximeter, Spectros Corporation 510(k) Numbers: K040684, K081233 moorVMS-LDF Laser Doppler Blood Flow and Temperature Monitor, Moor Instruments Ltd 510(k) Number: K083082

Description of the Device

The moorVMS-OXY is a device for taking non-invasive measurements of tissue hemoglobin (oxy-Hb and deoxy-Hb) and oxygen saturation (SO_2), together with tissue temperature. It is based on the theory of white-light reflectance spectroscopy and its measurement relies on spectrophotometric principles that relate light absorption to chromophore concentrations.

Measurements are taken using probes which are placed in contact with the tissue at the measurement site. Optical fibres are used to deliver illumination light to the tissue and collect reflectance light to the instrument for processing. The moorVMS-OXY™ analyses the back scattered reflected light in the wavelength range of 500 to 650nm and calculates tissue oxygenation by matching the collected spectra to the absorption curves from known concentrations of oxygenated / deoxygenated hemoglobin. This is to allow a rapid and accurate measurement of oxygenation saturation SO_2 (%), total hemoglobin and oxygenated / deoxygenated hemoglobin levels in the sample volume.

When used in conjunction with a moorVMS-LDF laser Doppler blood flow monitor, the moorVMS-OXY can also be used for the simultaneous measurement of tissue oxygen saturation and blood flow in microcirculation using a combined probe.

Intended Use

The moorVMS-OXY monitor is a non-invasive monitoring system that measures tissue oxygen saturation and tissue temperature in microcirculation. It is intended to noninvasively and continuously measure approximated value of hemoglobin oxygen saturation in superficial tissues for clinical research applications. The clinical value of measurements in disease states has not been demonstrated. The moorVMS-OXY monitor should not be used as the sole basis for diagnosis or therapy.

The moorVMS-OXY monitor can also be used for the simultaneous measurement of tissue oxygen saturation and blood flow in microcirculation using a combined probe in conjunction with a moorVMS-LDF laser Doppler blood flow monitor.

Substantial Equivalence

Technological Characteristics

Both moorVMS-OXY™ and the predicate device T-Stat 303 use the white light reflectance spectroscopy technique for tissue oxygenation measurements. They both use a white LED as a light source with the light transmitted to the skin through an optic fibre or a collimate lens. Both devices analyse the back scattered light returning from tissue, after having passed through the tissue, for hemoglobin in its oxygenated and deoxygenated forms in the optically sample region.

Both devices analyse the reflected light in the visible wavelength range and calculate tissue oxygenation by matching the collected spectra to the absorption curves from known concentrations of oxygenated / deoxygenated hemoglobin. They both measure light at hundreds of wavelengths rather than 4 or fewer wavelengths in other similar devices. An increase in the number of wavelengths used for calculation increases reliability and accuracy of tissue oxygen saturation SO_2 measurements and allows for an assessment of data quality.

The moorVMS-OXY probes may optionally incorporate a thermistor temperature sensor which allows local tissue temperature to be measured simultaneously with tissue oxygenation. This is intended to allow researchers to verify that constant measurement conditions are maintained during an experiment.

The moorVMS-OXY probes may also optionally integrate a laser Doppler sensor into a combined probe. When used in conjunction with a moorVMS-LDF laser Doppler monitor (K083082), it can provide the simultaneous tissue oxygen and blood flow measurement.

K112826

Indication for Use

The moorVMS-OXY™ has the same indication for use as the predicate device T-Stat 303 tissue oximeter for tissue oxygenation measurement in superficial tissue.

With use of a combined probe and/or an integrated temperature sensor, the moorVMS-OXY™ has the same indication for use as the predicate device moorVMS-LDF laser Doppler blood flow and temperature monitor. They both are intended for tissue blood flow and temperature measurement in microcirculation.

Performance Data

The extensive functionality and performance testing have been conducted for the moorVMS-OXY to verify its adherence to the requirements. The moorVMS-OXY monitor and its embedded software have been evaluated at the unit, integration and system level to validate its satisfaction of the functional specification. The moorVMS-OXY has been subjected to both in vitro and in vivo testing to determine its substantial equivalence to the predicate device, Spectros T-Stat 303 for tissue oxygen measurement.

The moorVMS-OXY is designed to comply with the requirements of electrical safety, LED light safety, electromagnetic compatibility and biocompatibility. It has the same levels of biocompatibility, LED light and electrical safety as the predicate device T-Stat 303. The difference is that the moorVMS-OXY probes are supplied in a non-sterile state for multiple uses while T-Stat 303 probes are available sterile for single use.

The tissue oxygen and laser Doppler blood flow combined probes have been tested for simultaneous tissue oxygen and blood flow measurement. The results show that there is no interference between the tissue oxygen and blood flow measurements, and the moorVMS-OXY combined probes can provide simultaneous tissue oxygen and blood flow measurement when they are used in conjunction with a moorVMS-LDF laser Doppler blood flow monitor.

Conclusions

Based on the design, technological characteristics, performance and functional testing and intended use, it can be concluded that the moorVMS-OXY tissue oxygen monitor is substantially equivalent to the predicate device, T-Stat 303 Tissue Oximeter, in terms of effectiveness and safety for tissue oxygen measurement in superficial tissues. When used with a moorVMS-LDF monitor, the moorVMS-OXY combined probes are substantially equivalent to the predicate device, moorVMS-LDF laser Doppler blood flow monitor and its associated probes for tissue blood flow and temperature measurement in microcirculation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 10 2012

Moor Instruments Ltd
c/o Dr. Xiabing Huang
Millwey
Axminster, Devon
United Kingdom EX135HU

Re: K112826
Trade/Device Name: moorVMS-OXY Tissue Oxygen and Temperature Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: August 31, 2012
Received: September 4, 2012

Dear Dr. Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K112826

Device name: moorVMS-OXY Tissue Oxygen and Temperature Monitor

Indications for use:

The moorVMS-OXY monitor is a non-invasive monitoring system that measures tissue oxygen saturation and tissue temperature in microcirculation. It is intended to noninvasively and continuously measure approximated value of hemoglobin oxygen saturation in superficial tissues for clinical research applications. The clinical value of measurements in disease states has not been demonstrated. The moorVMS-OXY monitor should not be used as the sole basis for diagnosis or therapy.

The moorVMS-OXY monitor can also be used for the simultaneous measurement of tissue oxygen saturation and blood flow in microcirculation using a combined probe in conjunction with a moorVMS-LDF laser Doppler blood flow monitor.

Prescription Use: Yes (Part 21 CFR 801 SubpartD)	AND/OR	Over-The-Counter Use: No (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112826